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A Short Description of Glycinebetaine (Bluestim[®])

Glycinebetaine (= betaine) is a natural product derived from sugar beet molasses. Sugar beet contains 0.2 – 0.3% betaine. Extraction of betaine from sugar beet can be divided into three main stages – production of sugar beet molasses from sugar beet, extraction of betaine rich fraction from sugar beet molasses using water as eluent and finally refining and crystallisation of betaine rich fraction to crystalline betaine to give Bluestim[®]. No additives or preservatives are used. Traces of salts and sugars can be found.

Glycinebetaine occurs naturally in many organisms including several plants. In the plants glycinebetaine acts as an osmoprotectant by adjusting the osmotic balance inside the plant cells and tissues. By this natural defence mechanism, Bluestim[®] (glycinebetaine) helps the plants to overcome the environmental stresses caused by heat, salinity, drought and cold, which are the worst enemies of plant productivity.

Betaine (CAS No. 107-43-7) has been determined to be generally recognized as safe (GRAS) for use as flavour modifier in all foods and beverages by the expert Panel of Flavour and Extract Manufacturers Association (FEMA) of the United States.

Pursuant to the OFPA definition, glycinebetaine is considered as 'Agricultural product'. Also in line with the Definition of Materials Decision Tree glycinebetaine is defined as 'Agricultural product'. As to the Final Rule, a substance like glycinebetaine would be defined as 'Non-Agricultural, Non-Synthetic Substance'. Finally, according to the NOSB's Proposed Decision Tree to Distinguish Synthetic and Non-Synthetic Substances (OMRI Standards Manual 2007) glycinebetaine is considered as a 'Non-Synthetic substance'.

VERDERA OY

Docket No. AMS-TM-07-0118

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November 26th, 2007

COMMENTS ON PROPOSED NOSB RECOMMENDATIONS

Betaine in the “Universe” of Materials

Agricultural and Non-agricultural

Our specific example substance is betaine (=glycinebetaine) derived from sugar beet molasses. Betaine is extracted from sugar beet via production of sugar beet molasses from sugar beet, extraction of betaine rich fraction from sugar beet molasses using water as eluent and finally refining and crystallisation of betaine rich fraction to crystalline betaine.

Taking betaine through the two different definitions (OFPA vs. Final Rule) gives two different results:

1. The Organic Food Production Act (OFPA) defines agricultural products as “any agricultural commodity or product, whether raw or processed, including any commodity of product derived from livestock that is marketing in the United States for human or livestock consumption”.

- **Betaine is derived from sugar beet by extracting (which is included in the OFPA definition of ‘Processing’) and is marketed in the United States for human and livestock consumption.**
 - **Betaine is ‘Agricultural Product’**

2. Definition of ‘Non-Agricultural, Non-Synthetic Substance’ from Final Rule: “A substance that is not a product of agriculture... For the Purpose of this part, a non-agricultural ingredient also includes any substance such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.”

- **Betaine defined as ‘Agricultural product’ according to the OFPA determination is then defined as non-agricultural, non-synthetic substance by the examples within the Final Rule definition of non-agricultural, non-synthetic substances (betaine is extracted from sugar beet (agricultural product), the identity of which can not be recognized in the extract).**

The Joint Committee’s opinion: “Definitions in the Final Rule for Agricultural product and Non-agricultural substances are inconsistent and do not provide clear guidelines for evaluating substances as an ‘agricultural product’ versus ‘non-agricultural substance’.”

Verdera agrees with the Joint Committee and supports its consideration of the possibility of recommending a deletion of the definition of ‘Non-Agricultural Substance’ or at least the examples within the definition.

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COMMENTS ON PROPOSED NOSB RECOMMENDATIONS

Definition of Materials Decision Tree

Taking betaine through the Definition of Materials Decision Tree:

Is the substance or product in question derived from plant or livestock, and marketed in the US for human or livestock consumption?

Yes. Glycinebetaine (= betaine) is extracted from sugar beet molasses and marketed in the US both for human and livestock consumption.

Has the substance been processed to the extent that its chemical structure has been changed?

No. Betaine is chromatographically extracted from sugar beet molasses using water as eluent and finally refined and crystallised to produce crystalline betaine. The chemical structure of betaine does not change during the separation, purification and crystallisation.

Have any other ingredients (additives, carriers, preservatives) been added to the substance and remain in the final product?

Not any. No additives or preservatives are used.

→ Betaine is 'Agricultural Product'

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COMMENTS ON PROPOSED NOSB RECOMMENDATIONS

NOSB's Proposed Decision Tree to Distinguish Synthetic and Non-Synthetic Substances (OMRI STANDARDS MANUAL 2007)

SUBSTANCE: Glycinebetaine (a.i. of Bluestim®)

(1) Is glycinebetaine derived from a natural source?

Yes. Glycinebetaine is a natural compound derived from sugar beet molasses.

(2) Does extraction of glycinebetaine from its source by chemical or physical methods occur?

Yes. Glycinebetaine is separated and purified in a number of process steps including chromatographic separation, where water is used as an eluent. After this the glycinebetaine is crystallised to produce Bluestim.

After the process of extraction is complete:

(3) Has glycinebetaine been transformed into a different substance via chemical change (excepting substances formed via naturally-occurring biological process)?

No. It is the same, stable compound as it is in its natural source, sugar beet.

(4) Has glycinebetaine been altered into chemical form that doesn't occur in nature?

No. It is the same, stable compound as it is in its natural source, sugar beet.

(5) Are any important functional properties of glycinebetaine altered by process?

No. It is the same, stable compound as it is in its natural source, sugar beet.

(6) Does glycinebetaine contain a significant level of a synthetic substance not on the National List?

No. It is 97% glycinebetaine, moisture and traces of salts and sugar derived from sugar beet.

(7) Is formulation needed to produce an agricultural or handling input?

No. Glycinebetaine is separated and purified in a number of process steps including chromatographic separation, where water is used as an eluent. After this the glycinebetaine is crystallised to produce Bluestim. Nothing is added to the compound. The chemistry or functional properties are not altered by any method.

Conclusion: Glycinebetaine is a non-synthetic substance.